Amendments to the Drawings:

The attached replacement sheet includes changes to Fig. 1. Fig. 1 is amended to identify an exemplary flexible section 80 and knee opening 81.

REMARKS

Claims 1, 14, 15, 17, 18, 22, 24-26, 28 and 29 are amended. Claim 31 is added. Claims 2, 21, 23 and 27 are cancelled without prejudice. Upon entry of this amendment, claims 1, 3-20, 22-26 and 28-31 will be pending.

Claim Amendments in General

Independent claims 1, 15, 18, 22, 25 and 29 are amended to emphasize that the apparatus of this invention is for carrying out sequential compression vascular therapy on a limb of a patient. These claims further state that applicant's sleeve includes a first portion (e.g., a thigh portion) with a first expandable chamber and a second portion (e.g., calf portion) with second and third expandable chambers. The three expandable chambers are arranged with respect to each other lengthwise along the sleeve to move blood lengthwise of the limb. Further, the claims are amended to state that the sleeve is torn along perforations to completely remove the first portion of the sleeve from the second portion of the sleeve while leaving the second portion of the sleeve intact for delivery of fluid from the pressurized source to the second and third expandable chambers, also arranged with respect to each other lengthwise along the sleeve, to permit sequential compression vascular therapy on the limb after the first portion of the sleeve is removed.

What applicant has achieved is surprising. Normally, tearing an article apart destroys the unity of the device and its functionality. However, applicant has used what would ordinarily be considered to be a destructive action and turned it into an advantage. Specifically, applicant has invented a compression sleeve which is intentionally designed to be torn apart, thereby irreversibly destroying the unity of the sleeve, while still leaving one portion intact and capable of carrying out sequential compression on the limb of a patient. The surprising and unpredictable nature of this result is strong evidence of non-obviousness. *KSR International Co. v. Teleflex Inc.*

The benefits of the present invention include greater comfort for the patient and reduced cost to the hospital. For example, a patient may be prescribed a mixed vascular therapy starting with the use of a full-length compression sleeve, followed by a period of time using a knee-length sleeve. With the tear-away perforations of the present

invention, there is no need for the hospital to replace the full-length sleeve with a new knee-length sleeve. The patient can use the same sleeve (with the thigh portion removed) to complete the prescribed sequential compression vascular therapy. Removal of a portion of the sleeve also increases the comfort and mobility of the patient. These many advantages and commercial success of applicant's product further support the non-obviousness of applicant's claimed invention.

Claims 14, 17, 24, 26, 28, 29 and 31 are also amended to recite additional details of applicant's compression apparatus, as discussed later.

Claim Rejections - 35 USC §103

Claims 1, 3-7, 11-15, 18-20, 22, 24-26 and 28 are rejected as unpatentable over Islava (6,719,711) and Poole et al. (4,624,248).

The Islava patent is directed to an inflatable splint which is used to immobilize a broken limb such as an arm. The Islava device has two or more rows of latitudinal air chambers 22 which are inflated by conventional blow spout 18. The rows of chambers are separated by perforated welds 40, 42 along which the splint may be torn partially across the splint to form two U-structures which can be used as shown in Figs. 3 and 4. The U-structures thus formed remain connected by a central hinge area 29 of the splint. Islava fails to show or suggest applicant's claimed compression device for a number of reasons.

First, Islava's splint is not constructed to carry our sequential compression vascular therapy on a patient. It will be noted in this regard, that the three expandable chambers in applicant's sleeve are arranged with respect to each other lengthwise along the sleeve so that sequential expansion of the chambers moves blood lengthwise of the limb of a patient. Further, applicant's sleeve is configured such that the second portion of the sleeve (incorporating two of the expandable chambers arranged with respect to each other lengthwise along the sleeve) remains intact after the first portion of the sleeve is torn away. As a result, the second portion of the sleeve may be used to continue a sequential compression vascular therapy by sequentially expanding the second and third

chambers. Islava's chambers are not arranged to permit any such operation, either before or after the splint is torn.

Further, unlike applicant's claimed design where the perforations extend continuously across the sleeve to allow a first portion of the sleeve to be completely removed, the entire emphasis in Islava is toward only a partial tearing of the splint along the perforated weld 40, 42. In this way, a center portion 29 of the splint remains intact so that it can function as a hinge. See for example column 4, lines 1-5, stating that in the preferred embodiment, the latitudinal welds do not extend across the entire width of the splint so that a center portion of the splint remains undivided; column 4, lines 53-61, stating that the center portion shown in Fig. 1a serves as a flexure upon which the two U-shaped portions 50, 60 bend toward or away from one another; and column 6, lines 27-29, stating that the center portions shown in Fig. 6 serve to couple the rows of air chambers together and thus keep the splint as "one integral piece."

The examiner contends that Islava suggests completely removing one portion of the splint from another based on the following statement in col. 4, lines 53-55:

> "detaching one portion 50 from another portion 60 also enables each portion to form a structure independently from the other."

The examiner suggests that "if the different portions were not completely removable they would not be 'independent' as recited." Applicant respectfully disagrees.

First of all, the quoted passage is taken from a paragraph which leads off referring to the construction "shown in Figs. 1a, 1b and 3." Figs. 1a and 1b show that the perforated welds 40, 42 do not extend through the central portion 29 of the sleeve. The patent further states later in that same paragraph (lines 59-61):

> "By detaching the portions 50, 60 along the perforated weld 40, the second portion 60 may be folded into a U-structure first while the first portion remains unfolded, or vice versa. The unwelded center portion 29, as shown in Fig. 1a, serves as the flexure upon which the two portions 50, 60 bend toward or away from one another."

It is apparent from this passage that the two portions 50, 60 remain connected by the hinge portion 29 even after the portions 50, 60 are "detached" and folded into U-structures.

Thus, the word "independently" used in the passage quoted by the examiner does not mean that the two splint portions 50, 60 can be completely separated from one another, but instead means that the two splint portions can be formed into separate U-structures which can moved relative to one another and used to cover two different portions of a limb. This conclusion is further supported by the following statement in col. 5, lines 10-14 of Islava:

> "The perforated latitudinal weld 40 allows one portion 50 to be partially detached from another portion 60 so as to enable the portions 50, 60 to bend toward or away from each other while independently maintaining their respective U-structures." (Emphasis supplied)

Nor would it have been obvious to one of ordinary skill to completely and irreversibly separate the two portions 50, 60 of Islava. The express purpose of Islava's splint is to immobilize and stabilize an injured limb, particularly a bent limb as shown in Figs. 3 and 4 (see col. 1, lines 54-61; col. 5, lines 1-5). To do this, the splint is designed to "encompass" and "envelop" the joint after the splint is partially torn (see col. 4, lines 27-31 and col. 5, lines 18-21). Clearly, the hinge portion 29 assists in achieving these objectives, i.e., immobilizing, stabilizing, encompassing and enveloping the joint after the splint is partially torn to form two U-structures. On the other hand, tearing through the hinge portion 29 and thus destroying it would eliminate the ability of the splint to immobilize, stabilize, encompass and envelop the injured limb at the joint.

Still further, the skilled person would recognize that if Islava's perforated weld 40 were extended to run continuously across the splint from one side of the splint to an opposite side of the splint, i.e., through the hinge 29, the splint could not be properly inflated because the weld 40 would block the flow of air into the air chambers located on the side of the weld opposite the blow spout 18. Alternatively, if an air passage was

provided across the weld to allow inflation of all air chambers, then tearing along the perforations would breach the passage and the entire splint would deflate. In short, any attempt to extend the perforated weld 40 completely across the splint would render the splint inoperable for its intended purpose. (See MPEP 2143.01(V) stating that "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.) For this additional reason, Islava cannot possibly teach a complete separation of the portions 50, 60 from one another.

The examiner also relies on Poole et al. in making his rejection. Poole et al. describe a pressure garment which is used to counteract internal bleeding conditions and hypovolemia "by developing an encircling pressure around the legs and abdomen of a victim" (col. 1, lines 13-15). The garment is divided into an upper section 12 adapted to be operatively positioned around the wearer's abdomen, and a pair of lower sections 14 adapted to be similarly positioned around the wearer's legs (col. 2, lines 25-29). The two sections 12, 14 are detachably interconnected by mating zipper components 16. The zipper connections are designed to be opened to allow medical personnel to gain access to certain arteries located for example at 38 (column 3, lines 14-18). Further, the zipper connections 16 allow for easy replacement of damaged modular components without having to scrap the entire garment (column 3, lines 22-25).

The examiner contends that it would have been obvious in view of Poole et al. to extend the perforations of Islava's sleeve continuously across the sleeve to completely separate the different portions of the sleeve. Applicant respectfully disagrees. As noted above, completely separating the two portions 50, 60 of Islava's splint would destroy the hinge 29. Further, tearing across the unwelded hinge 29 of Islava's design would result in deflation of the splint, rendering the device useless for its intended purpose. Under these circumstances, the skilled person would never modify Islava in the manner suggested by the examiner.

Further, like Islava, Poole et al. completely fails to teach applicant's claimed construction in which first, second and third expandable chambers are arranged with respect to each other lengthwise along the sleeve such that sequential expansion of the chambers moves blood lengthwise of the limb. Instead, the garment described in Poole et

al. comprises an abdomen section 12 having a chamber 22 and two leg sections 14 with chamber 22'. The abdomen chamber 22 is arranged longitudinally with respect to the two leg chambers 22', but the two leg chambers 22' are arranged laterally with respect to one another, not lengthwise relative to one another. This difference is important. The advantage of applicant's claimed longitudinal chamber arrangement is that the second portion of the sleeve can be used to carry out a sequential compression vascular therapy even after the first portion of the sleeve is removed from the second portion of the sleeve. This is accomplished by sequentially inflating the two (or more) chambers of the second portion of the sleeve, these chambers are also arranged with respect to each other lengthwise along the sleeve to move blood lengthwise of the limb. In contrast, if the abdomen section 12 of Poole et al.'s garment is removed, the only remaining expandable chambers are the two leg chambers 22', and these are arranged side-by-side on two different sleeves, not lengthwise with respect to one another to move blood along the length of the limb.

For at least these reasons, claims 1, 3-7, 11-15, 18-20, 22, 24-26 and 28 are not obvious in view of Islava and Poole et al., whether considered individually or in combination.

Claims 8-10 are rejected as unpatentable over the references as applied to claim 1 and further in view of Dye (5,795,312).

Dye shows a compression sleeve with a plurality of longitudinally disposed inflatable chambers 38a-38f. Dye fails to disclose perforations extending across the sleeve to allow the sleeve to be completely torn to remove one portion from the other. Accordingly, claims 8-10, which depend either directly or indirectly from claim 1, are submitted to be patentable for at least the same reasons as claim 1.

Claims 1, 3-11, 13-20, 22, 24-26 and 28-30 are rejected as unpatentable over Dye (5,795,312) in view of Islava (6,719,711), Poole et al. (4,624,248) and Arkans (6,062,244).

The examiner contends that it would have been obvious to separate different parts of Dye's sleeve from one another in order to accommodate different needs of different

patients. Applicant respectfully disagrees. Full length and knee length compression sleeves for use in vascular therapy have been sold separately for many years. The concept of using one sleeve which can be torn apart and still function as claimed by applicant is unique. Indeed, surprising.

Nor would it have been obvious in view of either Islava or Poole et al. to modify Dye to include applicant's claimed perforations. As explained above, Islava's perforations do not extend completely and continuously across the splint. Rather, the perforations are configured for allowing two U-structures to be independently formed and moved while remaining connected by the hinge 29. Thus, Islava actually teaches away from modifying Dye as the examiner contends.

The Poole et al. patent is directed to a garment having modular sections 12, 14 that can be connected, disconnected *and reconnected*. The patent emphasizes the advantage of this arrangement, as follows:

> "... the zipper connections 16 are designed to be opened to allow medical personnel to gain access to critical arteries..." (col. 3, lines 14-16)
>
> "The zipper connections 16 allow for easy replacement of damaged modular components, without having to scrap the entire garment." (col. 3, lines 22-25.)

Thus, at first glance, Poole et al. might suggest the possibility of modifying Dye to include a zipper to permit disconnection and reconnection of two parts of the compression sleeve. But a zipper connection is a far cry from using perforations to tear one sleeve portion from another. Disconnection by tearing, which destroys the connection of the sleeve portions and negates reattachment, would defeat the very reason for using a zipper connection in the first place. It would be entirely inappropriate and counter to the purpose of the Poole et al. invention to include "tear away" connections between the components.

Applicant's also disagrees with the examiner's contention that the Poole et al. reference teaches "being able to remove one section of the sleeve to be able to use the remaining sleeve alone as desired." In use, the abdomen and leg sections 12, 14 of Poole

et al.'s garment remain connected, as is evident from Fig. 1 showing the zipper partially opened to provide access to critical arteries. The patent further discloses in col. 3, lines 14-18 that this access is accomplished "without first having to deflate and remove the garment" (col. 3, lines 17-18). It is clear, therefore, that both sections 12, 14 are connected and function as a single unit during this procedure. Poole et al. disclose complete disconnection of the sections 12, 14 only for the purpose of "easy replacement of damaged modular components, without having to scrap the components" (col. 3, lines 22-25). One of ordinary skill would recognize that any such replacement would occur when the garment is not in use. There is nothing in Poole et al. that suggests the desirability of completely separating one section from another for the purpose of allowing one section to operate independently without the other, much less to perform sequential compression vascular therapy on the limb of a patient, as claimed by applicant.

Still further, completely removing one portion of Dye's sleeve as suggested by the examiner would not be obvious for the additional reason that any such removal would render Dye's sleeve inoperable for its intended purpose. It will be noted in this regard that Dye's sleeve is connected via a connector 48 to a controller (not shown) for supplying pressurized air to the sleeve (see column 3, lines 33-35). The controller operates in conventional fashion to sequentially inflate the various sections of the sleeve (column 4, line 65 to column 5, line 10). Completely removing a portion of Dye's sleeve by tearing along a line of perforations, as suggested by the examiner, would require disconnection of the fluid conduit associated with the removed portion (e.g., conduit 46d). The skilled person would know that any such disconnection would be immediately sensed by the controller and trigger an alarm program resulting in the stoppage of further flow of pressurized fluid to the sleeve. The fact that removal of a portion of Dye's sleeve would render the device inoperable is strong evidence of non-obviousness (MPEP 2143.01(V)).

The examiner also cites the Arkans patent, which shows a prior art compression device 10 comprising a foot cuff 36 and a calf cuff 38 connected by tubing to a controller unit 20. The tubing includes two tubing sets 30, 32 connected to one another by connectors 28, 29. The patent discloses replacing the prior art connectors of Fig. 1 with a new connector unit 40 which includes mating upstream and downstream connectors 42,

44. The upstream connector 42 is connected to the controller by tubing as shown in Fig. 1 (column 5, lines 9-12), and the downstream connector 44 is connected to respective cuffs 36, 38 by downstream tubes 50a, 50b. Preferably, shut-off valves 60a, 60b are positioned within the upstream connector 42 and block fluid flow from the controller when the connectors are disconnected (column 5, lines 44-49). The downstream connector 44 is configured to open the shut-off valves when the connectors are re-connected to permit flow to the cuffs (column 5, lines 50-63). Arkans is completely devoid of any teaching of a perforation to tear a first sleeve portion from a second sleeve portion. Accordingly, this reference cannot make applicant's claimed invention obvious.

For these reasons, claims 1, 3-11, 13-20, 22, 24-26 and 28-30 are not obvious in view of Dye, Islava and Poole et al., whether considered individually or in combination.

Claim 28, which depends from claim 1, is also amended and defines patentable subject matter for the additional reason that it is directed to a specific and unique tubing/connector/quick disconnect port arrangement. This arrangement comprises a single connector for connecting a pressurized fluid source to a first tubing, a second tubing and a third tubing for delivering pressurized fluid from the source to respective first, second and third expandable chambers. Further, the first tubing comprises a quick disconnect port (e.g., at 70 in Fig. 3 of the application) to permit easy removal of the first tubing from a downstream side of the connector when the first portion of the sleeve is removed from the second portion of the sleeve.

Dye, Islava, Poole et al. and Arkans fail to show any such arrangement. Dye shows a connector 48 and a plurality of tubes 46a-46d leading to expandable chambers, but there is no disclosure that any of the tubes can be disconnected from the connector. Islava has only one blow tube 18, and it appears to be permanently attached to the splint. Poole et al. disclose a plurality of pressure relief valves 28 and shut-off valves 32 which the examiner characterizes as "valve connectors." The advantage of applicant's design is that there is only one connector coupling the source of pressurized fluid with the first, second and third tubing elements. In Arkans, the two downstream tubes 50a, 50b supplying fluid to the cuffs 36, 38 remain attached to the downstream connector 44 at all times. There is no disclosure or suggestion whatsoever that one tube can be removed from the downstream side of the connector 44.

The connector/tubing/quick disconnect port arrangement of claim 28 is efficient, economical, and allows the first portion of the sleeve to be easily removed from the second portion of the sleeve. Accordingly, claim 28 is submitted as patentable for this addition reason.

Claim 29 also includes the connector/tubing/quick disconnect port arrangement of claim 28 and is allowable for all of the same reasons. In addition, claim 29 states that the connector comprises a fluid port and a valve which functions to only partially close the fluid port when the first tubing leading to the tear-away portion of the sleeve is removed from the connector. Because the valve only partially closes, fluid is able to continue to flow from the fluid port, and inflation and deflation of the two (or more) chambers in the second portion of the sleeve may continue without interruption. In this regard, feedback information to the controller is necessary to achieve proper operation. If a portion of the sleeve is removed, this feedback is interrupted and would normally cause the controller to discontinue operation. However, when the sleeve is equipped with the valve connector of claim 29, pressurized fluid continues to flow through the fluid port even after a portion of the sleeve is torn away and the associated tubing is disconnected from the fluid port of the connector. This continued flow simulates the flow characteristics prior to such disconnection so that the controller continues to operate as if the disconnection had not occurred. (For further details of this valve connection, see page 8, lines 12, lines 6-15 of the present application and Application Ser. No. 10/784,639, published August 25, 2005 as Publication No. 2005/01842645, incorporated by reference in this application).

The tubing/connector/valve feature of claim 29 is not shown or suggested by Dye, Islava, Poole et al. and Arkans for the same reasons expressed above in regard to claim 28. Further, these references are completely devoid of any showing or suggestion of a connector comprises a fluid port and a valve for only partially closing the fluid port when the first tubing leading to the tear-away portion of the sleeve is removed from the connector. For this additional reason, claim 29 as amended is believed to be allowable.

Claim 30 depends from claim 29 and states that the valve of the connector is movable when the first tubing is removed from the connector to reduce fluid flow from the pressurized fluid source through the fluid port of the connector to a level approximating flow to the first expandable chamber prior to removal of the first portion

of the sleeve from the second portion of the sleeve. As discussed above, this feature is advantageous because it maintains continuity with the pressurized fluid source so that vascular therapy can continue without interruption after the first portion of the sleeve is removed by tearing along the perforations. (See page 12, lines 6-15 of the present application.) There is no disclosure or suggestion of this feature in the cited prior art, and the examiner has expressed no reason for his rejection of claim 30.

Claims 11, 12 and 28-30 are rejected as unpatentable over Dye (5,795,312) in view of Islava (6,719,711), Poole et al. (4,624,248), Arkans (6,062,244) and Mitchell (2,638,915).

The examiner contends that it would have been obvious to modify Dye to include perforations as taught by Islava to disassemble the different sections of the sleeve so each section can be used independently as taught by Islava and Poole et al. Applicant respectfully disagrees for the reasons given above. Islava does not suggest completely removing one sleeve portion from another, and Poole et al. discloses a connection which can be used to disconnect and re-connect different sections 12, 14, unlike applicant's design where one sleeve portion is completely and irreversibly torn from another sleeve part.

Arkans and Mitchell are completely devoid of any teaching of perforations for tearinig a first sleeve portion from a second sleeve portion. Accordingly, these references do not make applicant's claimed invention obvious either alone or in combination with Dye, Islava and Poole et al.

Regarding claim 28, the examiner cites Mitchell as teaching a connector in which the downstream tubular pathways 14, 18 have quick disconnect ports 60 for individually disconnecting the downstream tubular pathways as desired or required. However, Mitchell fails to show or suggest a single connector connecting a first tubing, a second tubing and a third tubing to respective expandable chambers, as required by claim 28. Further, when the disconnect ports 60 are disconnected from the coupling unit 10, the valve members 98, 140 close to seal the coupling sections 59, 60 and the detached conduit sections 12, 14 (column 8, lines 60-64). There is no flow through the closed valve members 98 after disconnection. This is in direct contradiction to claims 29 and 30

which state that the connector comprises a fluid port and a valve for only partially closing the fluid port when the first tubing leading to the tear-away portion of the sleeve is removed from the connector. As discussed above, applicant's claimed valve feature is advantageous because allowing continued flow through the port vacated by the first tubing maintains continuity with the pressurized fluid source so that vascular therapy can continue without interruption after the first portion of the sleeve is removed by tearing along the perforations.

Claims 14, 17, 24, 26 and 31

Claims 14, 17, 24, 26 and 31 depend from independent claims which are allowable for the reasons discussed above. Further, these claims state that the first and second portions of the sleeve are connected by a flexible section of reduced width having a knee opening in it, and also that the perforations extend across the flexible section at a location below the knee opening[1]. This claim further distinguishes over Islava, disclosing perforations which do not extend across the hinge area 29, and the other cited art which fails to disclose perforations of any kind.

[1] Fig. 1 is amended to identify an exemplary flexible section 80 and knee opening 81.

CONCLUSION

In conclusion, applicant submits that the claims of this application define subject matter which is not obvious in view of the prior art, especially taking into account the surprising and unpredictable results achieved by the design.

Commissioner is hereby authorized to charge any fees due for additional claims to Deposit Account No. 19-0254. The Commissioner is also authorized to charge any additional fees due or credit any overpayment to Deposit Account No. 19-0254.

In view of the foregoing, favorable consideration and allowance of this application is requested.

Respectfully submitted,

Edward S. Jarmolowicz, Reg. No. 47, 238
Tyco Healthcare Group LP d/b/a Covidien
15 Hampshire Street
Mansfield, Mass 02048